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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,000	08/31/1999	DANIEL E. AFAR	1703-018.US1	4781

25225 7590 09/10/2002
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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/10/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/389,000

Applicant(s)

AFAR ET AL

Examiner

MINH-TAM DAVIS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-12, 14-50, 53-55, 60, 61, 68, 69 and 74-77 is/are pending in the application.
- 4a) Of the above claim(s) 5-12, 14-50, 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 54, 55, 60, 61, 68, 69 and 74-77 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 56-59, 62-67, 70-73.

Accordingly, claims 54, 55, 60, 61, 68, 69, 74-77 are being examined.

This application contains claims drawn to an invention nonelected with traverse in Paper No.9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following are the remaining rejections.

REJECTION UNDER 112, SECOND PARAGRAPH, NEW REJECTION

Claims 68-69 are indefinite, because it is not clear in claim 68 how a PHELIX protein having the amino acid sequence of SEQ ID NO:2, and yet that amino acid sequence is also a conservative substitution mutant of a protein having the amino acid sequence of SEQ ID NO:2.

REJECTION UNDER 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

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Claims 68, 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 68-69 are drawn to a polypeptide that is at least 90% identical to SEQ ID NO:2 over the entire length of SEQ ID NO:2, wherein the polypeptide is recognized by an antibody that specifically binds a PHELIX protein having the amino acid sequence of SEQ ID NO:2, that is a conservative substitution mutant of a protein having the amino acid sequence of SEQ ID NO:2.

Although the specification discloses conservative substitution (p.14), the specification does not disclose a polypeptide that has 90% identity to SEQ ID NO:2 by conservative substitution. Further, the specification does not disclose a polypeptide that is at least 90% identical to SEQ ID NO:2 over the entire length of SEQ ID NO:2.

REJECTION UNDER 35 USC 101, UTILITY

Rejection under 35 USC 101 of claims 54, 55, 60-61, 68, 69, 74-77 pertaining to lack of a specific and/or substantial utility remains for reasons already of record in paper No.16.

Applicant submits the Declaration by Dr. Challita-Eid. Applicant argues that the reference by Fu et al is an exception. Applicant further recites Oh et al, 2001, arguing that to the extent that Oh et al do not correlate mRNA and protein, they find that where

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mRNA is present the corresponding protein is as well. In the Declaration, Dr. Challita-Eid cites several references.

Applicant's arguments set forth in paper No.20 have been considered but are not deemed to be persuasive for the following reasons:

The submission of the Declaration by Dr. Challita-Eid is acknowledged. The arguments and the Declaration by Dr. Challita-Eid however could not be considered, because the cited references are not available.

REJECTION UNDER 112, FIRST PARAGRAPH, ENABLEMENT

Rejection under 35 USC 112, first paragraph of claims 54, 55, 60-61, 68, 69, 74-77 as related to the rejection under 35 USC 101, pertaining to lack of support from a specific and/or substantial utility remains for reasons already of record in paper No.16.

Applicant's arguments are the same as those under 101 rejection.

Applicant's arguments set forth in paper No.20 have been considered but are not deemed to be persuasive for the following reasons:

The same reasons under 101 rejection apply here as well.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

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MINH TAM DAVIS

September 8, 2002